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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,352	08/19/2005	Jan Matthias Braun	5008.01US01	3048
62274	7590 11/19/2007		EXAMINER	
DARDI & ASSOCIATES, PLLC 220 S. 6TH ST.			TONGUE, LAKIA J	
	SUITE 2000, U.S. BANK PLAZA MINNEAPOLIS, MN 55402		ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary		Application No.	Applicant(s)			
		10/519,352	BRAUN ET AL.			
		Examiner	Art Unit			
		Lakia J. Tongue	1645			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
WHIC - Exter after - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in a silver of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It is period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. lety filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)🖂	1) Responsive to communication(s) filed on <u>05 September 2007</u> .					
2a) <u></u> □	This action is FINAL . 2b)⊠ This action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposit	ion of Claims	•				
5)□ 6)⊠ 7)□	Claim(s) <u>1-22</u> is/are pending in the application. 4a) Of the above claim(s) <u>3,5,8,9 and 12-22</u> is/a Claim(s) is/are allowed. Claim(s) <u>1,2,4,6,7,10 and 11</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	are withdrawn from consideration				
Applicati	ion Papers					
10)⊠	The specification is objected to by the Examine The drawing(s) filed on <u>27 December 2004</u> is/al Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	re: a) \square accepted or b) \square object drawing(s) be held in abeyance. See ion is required if the drawing(s) is object.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority (under 35 U.S.C. § 119	•				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
	ot(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4)				
3) 🔯 Infor	mation Disclosure Statement(s) (PTO/SB/08) Pr No(s)/Mail Date 12/27/04.	5) Notice of Informal F 6) Other:				

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I claims 1, 2, 4, 6, 7, 10, 11, and 12, in the reply filed on September 5, 2007 is acknowledged. On October 22, 2007 a phone call was made to Mr. Curtis Herbert to clarify the additional invention election.

Applicant's further elected purified lipooligosaccharides from *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B.

The traversal is on the grounds that:

- 1) The medicament of claim 1 is distinct from the teaching of Gu et al. and thus novel, because claim 1 comprises the feature that the glycoconjugates or lipooligosaccharides are from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis*.
 - 2) Gu et al. have nothing to do with diseases caused by Neisseria meningitidis.
- 3) Gu et al. do not use the entire lipooligosaccharide, but instead truncated lipooligosaccharides which were subjected to de-esterification or removal of lipid A.
- 4) The medicament of claim 3 is linked to the medicament of claim 1 by the common technical feature lipooligosaccharides or glycoconjugates that comprise antigens cross-reactive to *N. meningitidis*.

Applicant's arguments have been considered but are not deemed persuasive.

With regard to Point 1, contrary to Applicant's arguments, when considered as a whole the inventions as defined above define a contribution over the prior art. Gu et al. (U.S. Patent 6,685,949 B1) demonstrate that the technical feature of the instant claims

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is known in the art. Gu et al. disclose compositions that comprise lipooligosaccharide from *Moraxella catarrhalis*. The LOS of Gu et al. is the same as that which has been claimed. Consequently, the LOS of Gu et al. in absence of evidence to the contrary, would necessarily be cross-reactive antigens to *Neisseria meningitidis*.

With regard to Point 2, claim limitations such as "for the treatment or prevention of diseases due to infection by *Neisseria meningitidis*" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

With regard to Point 3, while Gu et al. disclose the use of truncated lipooligosaccharides which were subjected to de-esterification or removal of lipid A instead of the entire lipooligosaccharide the instant claims are broadly drawn and encompass the lipooligosaccharides disclosed in Gu et al.

With regard to Point 4, while claims 1 and 3 possess similar technical features the claims are independent and distinct primarily because claim 1 comprises lipooligosaccharides or glycoconjugates from *Moraxella catarrhalis* and claim 3 comprises lipooligosaccharides or glycoconjugates from *Neisseria lactamica*.

The requirement is deemed proper and is therefore made FINAL.

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Claims 1-22 are pending. Claims 3, 5, 8, 9, and 12-22 have been withdrawn from further consideration as being drawn to non-elected inventions. Claims 1, 2, 4, 6, 7, 10, and 11 are under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on December 27, 2004 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto. However, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

3. Claim 1 is objected to because of the following informalities: Claim 1 recites language drawn to non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 4, 6, 7, 10, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in <u>In re Wands</u>, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the

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quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to a medicament for the treatment or prevention of diseases due to infection by Neisseria meningitidis, characterized in that it comprises purified lipooligosaccharides (LOS) from commensal Moraxella catarrhalis with cross-reactive antigens to Neisseria meningitidis of the serogroup B.

Breadth of the claims: The claims are broadly drawn and encompass a medicament for the treatment or prevention of any disease due to infection by Neisseria meningitidis, characterized in that it comprises any purified lipooligosaccharides (LOS) from commensal Moraxella catarrhalis with cross-reactive antigens to Neisseria meningitidis of the serogroup B.

Direction or guidance presented in the specification: The instant claims are drawn to a medicament for the treatment or prevention of any disease due to infection by Neisseria meningitidis comprising any purified lipooligosaccharides (LOS) from commensal Moraxella catarrhalis with cross-reactive antigens to Neisseria meningitidis of the serogroup B. To be a prophylactic medicament, said medicament must induce a protective immune response demonstrated by challenge experiments in an acceptable

animal model. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity against infection by Neisseria meningitidis. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing a condition. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced. The instant specification discloses the binding of antibodies to blood group antigens by Moraxella catarrhalis isolates (see pages 37-38), the ability to induce lower cytokine levels (see page 53), the binding of antibodies to blood group antigens and meningococcal immune type antibodies by Moraxella catarrhalis strains from adults and children (see page 52), anti-LOS antibodies from Moraxella catarrhalis, which were bactericidal, opsonophagocytic and anti-inflammatory, while those same anti-LOS antibodies were not for human serum absorbed with Moraxella catarrhalis (see pages 54-55; Tables 15 and 19). However binding of antibodies and ability to induce lower cytokine levels does not necessarily correlate to protective immunity. For example, HIV-1 induces the production of neutralizing antibodies but to date, there is no effective HIV-1 vaccine. The specification does not provide a demonstration where a pathogen free subject was administered the claimed composition and as a result the subject was protected from a given pathogen or condition due to infection by Neisseria meningitidis.

The specification, however, does not disclose treatment and/or prevention of a representative number of members of the genus to which the claims are drawn, such as

the condition being treated or prevented, the nature of the LOS, which eptiopes on the LOS are required and induce antibodies that are cross-reactive with serogroup B, the structure of the epitopes; or how the epitopes can be derived. Moreover, the specification does not disclose distinguishing and identifying features of a representative number of members of the genus to which the claims are drawn (i.e. which purified lipooligosaccharides are required to induce the recited cross-reactive antigens to *Neisseria meningitidis* of serogroup B) so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus. Therefore the specification fails to adequately describe at least a substantial number of members of the genus to which the claims are based.

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There is insufficient direction or guidance presented in the specification with regard to the prevention of any condition, particularly the prevention of a condition due to infection by *Neisseria meningitidis*. The demonstration of treating and/or preventing any condition due to infection by *Neisseria meningitidis* is required for the skilled artisan to be able to use the claimed method for their intended purpose. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of following the claimed method steps.

Presence or absence of working examples: There are no working examples, which suggest a method of treating and/or preventing (prophylaxis) any condition due to infection by Neisseria meningitidis comprising any purified lipooligosaccharides (LOS) from commensal Moraxella catarrhalis with cross-reactive antigens to Neisseria meningitidis of the serogroup B.

State of the prior art: The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2).

Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

Moreover, Greenspan et al. (Nature Biotechnology 17: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding.

Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot

determine whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other.

Quantity of experimentation necessary: The quantity of experimentation necessary would be undue. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

5. Claims 1, 2, 4, 6, 7, 10, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a medicament for the treatment or prevention of diseases due to infection by *Neisseria meningitidis*, characterized in that it comprises purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B.

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The claims are broadly drawn and encompass a medicament for the treatment or prevention of diseases due to infection by *Neisseria meningitidis*, characterized in that it comprises purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B. Moreover, the instant claims encompass a medicament for the treatment or prevention of any disease due to infection by *Neisseria meningitidis* comprising any purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B.

Moreover, the claims require the use of purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B that are not defined (i.e. they do not have possession of the LOS). To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed

invention. To adequately describe the genus of LOS, Applicant must adequately describe the purified lipooligosaccharides from commensal *Moraxella catarrhalis* that has the distinct capability to be cross-reactive with antigens to *Neisseria meningitidis* of the serogroup B

The specification, however, does not disclose treatment and/or prevention of a representative number of members of the genus to which the claims are drawn, such as the condition being treated or prevented, the nature of the LOS, which eptiopes on the LOS are required and recognized against serogroup B, the structure of the epitopes; how the epitopes can be derived, so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus. Therefore the specification fails to adequately describe at least a substantial number of members of the genus to which the claims are based.

Moreover, Greenspan et al. (Nature Biotechnology 17: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine

whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other.

A representative number of species means that the species that are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus.

See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual

reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention" (ld. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the Applicant had possession of the claimed invention at the time the instant application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4, 6, 7, 10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Gu et al. (U.S. Patent 6,685,949 B1).

The rejected claims are drawn to a medicament for the treatment or prevention of diseases due to infection by *Neisseria meningitidis*, characterized in that it comprises purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B.

Gu et al. disclose a vaccine comprising lipooligosaccharides isolated from *M. catarrhalis*. Gu et al. disclose that the LOS can be treated (detoxified) to remove esterified fatty acids or to remove lipid A to produce an oligosaccharide (see column 3, lines 42-48). Gu et al. disclose that in one embodiment, the fatty acids are removed with hydrazine or a mild alkaline reagent (see column 4, lines 52-53). Gu et al. disclose that the invention is a pharmaceutical composition that includes a vaccine conjugate in a pharmaceutically acceptable carrier, which may include an adjuvant (column 3, lines 64-66). Moreover, Gu et al. disclose that for vaccination, the vaccine can be administered transmucosal (i.e. intranasally). For intranasal administration, the formulation may be aerosolized (see column 14, lines 1-5 and 22-25).

The composition of Gu et al. is the same as the instantly claimed medicament.

The LOS from *Moraxella catarrhalis* necessarily has antigens that are cross-reactive to *Neisseria meningitidis* of the serogroup B.

Claim limitations such as "for the treatment or prevention of diseases due to infection by *Neisseria meningitidis*" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art.

See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

- 7. No claim is allowed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT 11/05/07

> ROBERT A. ZEMAN PRIMARY EXAMINER